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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/599,400 06/22/00 SAVITZKY

K 24286

EXAMINER

HM12/0208

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WASHINGTON DC 20005

MERTZ, P  
ART UNIT

PAPER NUMBER

1646  
DATE MAILED:

02/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/599,400

Applicant(s)  
Savitzky et al.

Examiner  
Prema Mertz

Group Art Unit  
1646



☒ Responsive to communication(s) filed on Nov 29, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-37 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-37 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

1. The preliminary amendment (Paper No. 10, 6/22/00) has been entered.
2. The restriction requirement of Paper No. 5 (9/29/00) has been reconsidered in light of the preliminary amendment and restriction to the following inventions has been reconstructed as follows:

#### ***Restriction/Election***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I-VIII. Claims 1-2, 5, 9-15, drawn to a nucleic acid encoding an alternative splicing variant of tumor necrosis factor receptor protein, an expression vector, and a host cell, classified in class 536, subclass 23.5.
  - IX-XVI. Claims 3-4, 12-15, 31-35, drawn to a splicing variant of tumor necrosis factor receptor protein, classified in class 530, subclass 350.
  - XVII-XXIV. Claims 6-8, 14-15, drawn to an antibody to a splicing variant of tumor necrosis factor receptor protein, classified in class 530, subclass 387.1.
  - XXV-XXXVI. Claims 16-17, 18-21, drawn to a method of detecting the presence of a nucleic acid encoding a splicing variant of tumor necrosis factor receptor protein in a sample, classified in class 435, subclass 6.
  - XXXVII-XXXXII. Claims 22-24, drawn to a method of identifying candidate compounds capable of binding a splicing variant of tumor necrosis factor receptor protein, classified in class 435, subclass 7.1.

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XXXXIII-XXXXVIII. Claim 25, drawn to an agonist of a splicing variant of tumor necrosis factor receptor protein, class and subclass undeterminable.

XXXXIX-LVI. Claim 26, drawn to an antagonist of a splicing variant of tumor necrosis factor receptor protein, class and subclass undeterminable.

LVII-LXIV. Claims 27-30, 36-37, drawn to a method of determining a splicing variant of tumor necrosis factor receptor protein in a sample using an antibody, classified in class 435, subclass 7.1.

Applicants are advised that claims 12-15 are improper Markush claims because the multiple elements recited therein are polypeptides, antibodies and nucleic acids, which do not share a common technical feature which is based on a common property or special technical feature not found in the prior art. These polypeptides, antibodies and nucleic acids are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art polypeptides or nucleic acids.

Inventions I-LXIV are distinct, each from the other because of the following reasons:

Inventions I-VIII, IX-XVI and XVII-XXIV, are independent and distinct, each from the other, because they are products, each of nucleic acids of SEQ ID NO:1-8, which possess characteristic differences in structure and function, that is distinct for each invention which cannot be exchanged. The nucleic acid of Group I can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the specific protein of interest, said protein having the

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amino acid sequence of SEQ ID NO:9. Only the nucleic acid of Group I can be used to prepare the protein of Group IX and no other protein. Similarly each of the nucleic acids in each of Groups II-VIII can only be used to produce recombinant protein of each of Groups X-XVI, respectively. The protein of Group IX can be used to make the antibody of Group XVII, or as used as a probe, or used therapeutically or diagnostically (e.g. in screening). Although the antibody of Group XVII can be used to obtain the nucleic acid of Group I, it can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or it may be used therapeutically. Therefore, each of the products in each of these Groups is an independent and distinct invention.

Inventions I-VIII and XXV-XXXVI are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of inventions I-VIII can also can be used in gene therapy or in recombinant production of the specific proteins of interest.

Inventions XVII-XXIV and LVII-LXIV and are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of inventions XVII-XXIV can also can be used in immunoaffinity chromatography to isolate each of the specific corresponding proteins..

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Inventions IX-XVI and XXXVII-XXXXII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of inventions IX-XVI can also be used as antigens in the production of specific antibodies.

Inventions I-VII, XXXVII-LXIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions IX-XVI and XXV-XXXVI, XXXXIII-LXIV, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions XVII-XXIV and XXXV-LVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

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Inventions XXXXIII-XXXVIII and XXV-XXXXII, LVII-LXIV, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions XXXXIX-LVI and XXV-XXXXII, LVII-LXIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions XXV-XXXXII and LVII-LXIV are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Prema Mertz*  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
January 22, 2001